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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David E. Milov

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EXAMINER

FERTIG, BRIAN E

ART UNIT

PAPER NUMBER

3694

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/658,878	MILOV, DAVID E.	
	<b>Examiner</b>	<b>Art Unit</b>	
	BRIAN FERTIG	3694	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Priority***

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: Provisional Application 60/410,282 was filed more than 12 months prior to the filing of the present application.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

#### With respect to claim 20

This claim recites means for plus function language. This language invokes the rebuttable presumption that applicant seeks treatment under 35 U.S.C. 112, sixth paragraph. Such treatment requires that applicant clearly identify particular structures or steps within the disclosure as the means for or steps for that applicant intends to claim (see MPEP § 2181). No such clear identification has been found, rendering the claim indefinite. For the purposes of examination below, it is assumed that applicant did not intend to invoke treatment under 35 U.S.C. 112, sixth paragraph. Applicant is advised to explicitly rebut the

presumption that 35 U.S.C. 112, sixth paragraph treatment has been invoked, amend the claims to remove the invoking language, or point out language in the disclosure that clearly identifies the particular structures or steps applicant intends to claim.

***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-11 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims recite material that, when given its broadest reasonable interpretation, embody programs and data structures, per se. Programs and data structures are non-statutory subject matter when not properly embodied (see MPEP § 2106.1). Further, these claims recite references to non-functional descriptive material. Examples include electronic documents and evidence levels. As claimed, this data is neither properly embodied (see above) nor does it impart functionality when employed as a computer component. (see MPEP § 2106.1)

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,307,262 to Ertel (Ertel).

With respect to claim 1

Ertel teaches:

A computer implemented medical database comprising:

a plurality of medical documents (i.e. cases), each of said plurality of documents having protocol information associated therewith (i.e. patient demographic, clinical, diagnostic, and procedure codes, see col 8, lines 45-52, col 9, lines 25-40) ; and

an evidence level associated with each of said plurality of documents, said evidence level being a measurement of the validity of the protocol information for a document (i.e. information pertaining to data quality, see col 16, lines 20-27).

With respect to claim 2

Ertel teaches:

A computer implemented medical database according to claim 1 (see rejection of claim 1 above), wherein the evidence level is based upon a plurality of factors, said factors including one or more of the following: controlled study data, cross-over trial data, and placebo study data, and common practice data. (i.e. disallowed value or error condition, non-

compliance with explicit requirements or published guidelines, see col 11, line 45-col 12, line 20)

With respect to claim 3

Ertel teaches:

A computer implemented medical database according to claim 2 (see rejection of claim 2 above), wherein: each evidence level is determined by a consensus among peers (see col 12, lines 5-20, note that explicit requirements and published guidelines are determined by a consensus among peers. See also col col 10, lines 46-55, note that additional evidence level indicators will be determined by further review of certain cases By claims payees and peer review organizations).

With respect to claim 4

Ertel teaches:

A computer implemented medical database according to claim 3 (see rejection of claim 3 above), wherein: each evidence level equals a percentage from 0% to 100% (see col 14, lines 5-54, note that reports are generated containing percentages and each case includes a data quality status).

With respect to claim 5

Ertel teaches:

A computer implemented medical database according to claim 4 (see rejection of claim 4 above), further including links to said protocol

information associated with each of said plurality of documents (see col 8, lines 45-52, note that because the cases are stored with their protocol information in a data base all of which are retrieved together for review, it is implicit that this information is linked).

With respect to claim 6

Ertel teaches:

A computer implemented medical database according to claim 5 (see rejection of claim 5 above), further including one or more concept unique identifiers associated with each of said plurality of documents (i.e. diagnoses and procedure codes, see col 8, lines 45-52, col 9, lines 25-40).

With respect to claim 7

Ertel teaches:

A computer implemented medical database according to claim 6 (see rejection of claim 6 above), further including one or more evaluation and management codes associated with each of said plurality of documents (i.e. Control information, see col 8, lines 45-52, col 9, lines 25-40)

With respect to claim 8

Ertel teaches:

A computer implemented medical database according to claim 7 (see rejection of claim 7 above), further including:

a computer-implemented user interface configured to access the computer implemented medical database (i.e. system

utility/utility program, see col 9, line 41-col 10, line 12, col 25, lines 55-68, col 27, lines 18-22 ), and

computer program coding for each of said plurality of documents, said computer program coding being configured to enable presentation of the document using the computer implemented user interface (see, col 27, lines 18-22, note that the interface allows the documents to be printed).

With respect to claim 9

Ertel teaches:

A computer implemented medical database according to claim 8 (see rejection of claim 8 above), further including: one or more templates, each of said one or more templates being configured for entry of the each of said plurality of medical documents, concept unique identifiers, and evaluation and management codes in the database (i.e. worksheets, see col 39, lines 45-60 and Tables 1A and B).

With respect to claim 10

Ertel teaches:

A computer implemented medical database according to claim 9 (see rejection of claim 9 above), further including: a document type identifier associated with each of said plurality of medical documents (see, col 8, lines 62-68, note that to prevent duplicate entry of a patient admission, it is implicit that a document type identifier be associated).



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With respect to claim 11

Ertel teaches:

A computer implemented medical database according to claim 10 (see rejection of claim 10 above), wherein the documents type identifier includes an indication of age for an intended reader of one or more of said plurality of documents (i.e Adm date, dis date, report date, see Table 1A).

With respect to claim 12

Ertel teaches:

A method for creating a medical database, said method comprising steps of:

assigning a topic (i.e. entering patient information, see col 8, lines 45-52);

writing a document on the topic (i.e. compiling case report including diagnosis, etc, see col 8, lines 45-52);

submitting the document to peers for review and assignment of an evidence level (i.e. peer review, see col 10, lines 46-55); and

entering the document and the assigned evidence level for the document in a computer accessible database (see col 8, lines 45-52 and col 12, lines 4-20, note the quality messages are stored).

With respect to claim 13

Ertel teaches:

The method according to claim 12 (see rejection of claim 12 above), said method further wherein the assigned evidence level is based upon a plurality of factors, said factors including one or more of the following: controlled study data, cross-over trial data, and placebo study data, and common practice data (i.e. disallowed value or error condition, non-compliance with explicit requirements or published guidelines, see col 11, line 45-col 12, line 20).

With respect to claim 14

Ertel teaches:

The method according to claim 13 (see rejection of claim 13 above), wherein the assigned evidence level is determined by a consensus among peers (see col 12, lines 5-20, note that explicit requirements and published guidelines are determined by a consensus among peers. See also col 10, lines 46-55, note that additional evidence level indicators will be determined by further review of certain cases By claims payees and peer review organizations).

With respect to claim 15

Ertel teaches:

The method according to claim 14 (see rejection of claim 14 above), said method further including steps of assigning a concept unique identifier with the document and entering the assigned concept unique identifier in

the database (i.e. diagnoses and procedure codes, see col 8, lines 45-52, col 9, lines 25-40).

With respect to claim 16

Ertel teaches:

The method according to claim 15 (see rejection of claim 15 above), said method further including steps of assigning a evaluation and management code with the document and entering the assigned evaluation and management code in the database (i.e. Control information, see col 8, lines 45-52, col 9, lines 25-40).

With respect to claim 17

Ertel teaches:

The method according to claim 16 (see rejection of claim 16 above), said method further including steps of assigning a critical data element with the document and entering the assigned critical data element in the database (i.e. DRG assignment information, see col 8, lines 53-61).

With respect to claim 18

Ertel teaches:

The method according to claim 17 (see rejection of claim 17 above), said method further including steps encoding the document into a format compatible with a user interface (see, col 27, lines 18-22, note the document is printed).

With respect to claim 19

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Ertel teaches:

A computer implemented medical database comprising a database means for storing a plurality of medical documents (i.e. database), associated protocol information (i.e. patient demographic, clinical, diagnostic, and procedure codes), and associated evidence levels (i.e. information pertaining to data quality), each of said plurality of documents having protocol information associated therewith, and each of said plurality of documents having an evidence level associated therewith (see col 8, lines 45-52, col 9, lines 25-40 and col 16, lines 20-27, note that because the cases data is stored in a data base and all associated with a case)

With respect to claim 20

Ertel teaches:

A computer implemented medical database according to claim 19 (see rejection of claim 19 above), further comprising a template for entering the plurality of medical documents, associated protocol information, and associated evidence levels into the database (i.e. worksheets, see col 39, lines 45-60 and Tables 1A and B).

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 5,715, 451 to Marklin teaching peer reviewed standards and US Patent 5,550,734 to Tater teaching a medical database system encompassing percentage scoring.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN FERTIG whose telephone number is (571)270-5131. The examiner can normally be reached on Monday - Friday 8:30am to 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Trammell can be reached on (571) 272-6712. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B.F./

/Mary Cheung/  
Primary Examiner, Art Unit 3694